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Behavioral interventions have focused primarily on early detection rather than the prevention of breast cancer; this trend is changing rapidly as chemoprevention agents, such as Tamoxifen, receive more attention. An important challenge is how to facilitate the review of Tamoxifen information among higher risk women who may benefit form its use. A second challenge is to understand how the format of conveying Tamoxifen's risks and benefits to affects women's (a) overall weighing of risk and benefits and (b) intentions use Tamoxifen. Whether a woman reviews information on Tamoxifen depends, in part, on how she interprets her BC risk. The purpose of this study is to test how the numerical format of conveying breast cancer (BC) risk and the risks and benefits of taking Tamoxifen as a chemopreventive agent individually and jointly affect women's intentions to sue Tamoxifen and talk to a health care provider about its use. Evaluating the effects of different formats, and understanding the psychosocial mechanisms through which they affect decision-making, will become increasingly important as more women consider Tamoxifen, other breast cancer chemopreventive agents (e.g., Raloxifen), and chemopreventive drugs for cancer more broadly.

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I. Introduction

The purpose of this study is to test how the numerical format of conveying breast cancer (BC) risk and the risks and benefits of taking Tamoxifen as a chemopreventive agent individually and jointly affect women's intentions to use Tamoxifen and talk to a health care provider about its use. The specific aims are to test how conveying (1) breast cancer risk as a frequency (e.g., 10 out of 10,000) or probability (e.g., .1%) affects perceived BC risks and negative emotions (e.g., fear, worry) about getting BC, the extent of processing information about Tamoxifen's risks and benefits (i.e., how much time is spent reviewing data on Tamoxifen), and intentions to use and talk to a health care provider about Tamoxifen use and (2) Tamoxifen's risks and benefits as frequencies or probabilities, individually and jointly interact with the BC risk format to affect women's weighing of the risks and benefits, intentions to use and talk with a health care provider about Tamoxifen use.

II. Body: Accomplishments as Outlined in the Approved Statement of Work

A. Development and pretesting of experimental and recruitment materials

In June 2003, we met with the study consultants to discuss and obtain feedback on study procedures, survey instruments and intervention materials.

In July 2003, under the direction of Duke's Educational Media group, we began development of a web-based program designed to present information on Tamoxifen's risks and benefits. The web program has been tested and is now ready for use.

In August 2003, we obtained a E-prime software program from colleagues at Decision Research (Oregon). The E-prime program is a combination of psychological software tools used to assess individual reaction time and thought processes related to specific information via the use of word/picture associations. For purposes of our study, E-prime will be used to assess participant's thoughts and feelings about their breast cancer risk and taking Tamoxifen.

In October 2003, we hired Shelly Epps, genetic counselor. Ms. Epps has been trained on details of the study protocol and has been very instrumental in assisting with the development of study materials.

All survey instruments including the baseline phone survey, lab questionnaires and follow-up questionnaires have been finalized and approved by the Duke University Medical Center Institutional Review Board (IRB).

As of May 6, 2004, we have received support from nine (9) Duke Gynecologists and Nurse Practitoners from which to obtain our patient sample and are currently contacting additional providers.

B. Conduct recruitment and experimental procedures (Months 3-33)

Our study is ready to begin participant recruitment, however, delays in doing so have been due to obtaining DOD IRB approval. A total of 8+months has transpired since obtaining Duke IRB approval and subsequently submitting materials to DOD IRB for review and approval. We received recent notification from the DOD reviewer on May 17, 2004 that further modifications were needed. Reponses to the reviewer's recommendations and supporting documentation were submitted via Fed ex on June 1, 2004.

C. No data analyses have been conducted.

III. Key Research Accomplishments

None

IV. Reportable Outcomes

No study analyses have taken place, therefore there are no outcomes to report at this time.

V. Conclusions

None

VI. References

None

VII. Appendices

None